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REMARKS

In the Office Action mailed 30 December 2003, pending claims 1 and 20 were objected to and rejected. Following entry of the instant amendment claims 1 and 20 are pending, with claims 2-19 and 21-36 canceled. Entry and favorable consideration of the pending claims is earnestly solicited so that the claimed invention may pass to timely issuance as U.S. Letters Patent.

Claim Rejections Under 35 U.S.C. §112, ¶ 1

Claim 1 and 20 stand rejected Under 35 U.S.C. §112, ¶ 1 and the amendment submitted on 25 November 2003 is objected to as introducing new matter.

In support of the rejection (and objection) the Examiner asserts that on the basis of page 4 (ll. 21) to page 5 (ll. 7) and page 23 (ll. 17-26) the Examiner was "unable to find the limitations" added to claims 1 and 20.

First of all, Applicant respectfully asserts that the 37-page specification (written description and 36 discrete claims), the drawings and all material inherent therein when viewed by a person of skill in the art – rather than the 18 and 8 lines of text referred to by the Examiner – represents the appropriate frame of reference for the instant rejection (and objection). Of course, Applicant merely needs to point out that FIG. 6 and FIG. 9 (and the corresponding written description – at page 22 and 28-29, respectively) clearly depict the relationship between blood pressure, heart rate and NID. In FIG. 6 the relationship is depicted wherein lower blood pressure corresponds to lower NID values. Also, the flow charts of FIG. 7 and FIG. 8 clearly elucidate the notion of a distinguishing relationship between heart rate, blood pressure and an adjustable

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NID used to deliver a cardioversion or defibrillation therapy. In addition, Applicant respectfully requests the Examiner to study the portions of the specification *not cited* (e.g., the rest of the Summary of the Invention at page 5 through page 6). Applicant suggests that much support can be cited in support of the claim limitations of the pending claims. However, rather than catalog the immense amount of support for the present invention wherein criteria are set forth for distinguishing between hemodynamically stable and unstable tachycardia Applicant simply avers that, from the start (i.e., the Background of the Invention at page 2, ll. 9-13) there can be no doubt that the claim limitations are expressly and inherently detailed in the application as filed. Accordingly, no new matter was previously submitted and the instant rejection (and objection) stands traversed. As a result same should properly be withdrawn.

Second, without question the notion of changing (i.e., lowering NID criteria) in the face of decreasing blood pressure is fully and expressly supported in the application as filed. Applicant also vigorously contends that logically and inherently *a lack of* decreasing blood pressure (i.e., a hemodynamically stable condition) - during collection of heart rate-based evidence of a tachycardia episode - is used according to at least one form of the present invention to increase the NID (essentially to tolerate the stable tachycardia - which could comprise a normal, exercise-induced "sinus tachycardia"). Applicant suggests that the Examiner re-read the application and in view of the foregoing, withdraw this ground of rejection (and objection) as unsupported.

Claims Rejections Under 35 U.S.C. §103

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Claim 1 and 20 stand rejected as being unpatentable over U.S. Pat. No. 5,458,622 to Alt (Alt) in view of U.S. Pat. No. 5,257,621 to Bardy et al. (Bardy).

After studying the combination posed by the Examiner, Applicant respectfully suggests that the Examiner repeatedly attempts to extend Alt from its primary if not exclusive focus of what is termed a complementary sensor. The complementary sensor of Alt is based exclusively on "activity" (as sensed by an accelerometer) and Alt only notes that an "indirect activity sensor" may also be used. Without explanation, however, the Examiner unilaterally shortened the phrase "indirect activity sensor" to "*indirect sensor.*" The Examiner cites the same *modified* passage from Alt *three times*. However, as clearly set forth in Alt such a complementary sensor is actually "an indirect sensor of physical exercise of a patient such as blood pressure" (col. 3, ll. 24-25 – emphasis added). Applicant suggests that the Examiner has unfairly modified or *characterized* Alt although Alt is devoid of any disclosure, depiction or enablement regarding lowering tachycardia detection criteria based solely on heart rate and blood pressure measurements of a patient. Moreover, Alt is devoid of any teaching regarding what type of blood pressure sensor should be chronically deployed into fluid communication with a patient, how a direct pressure signal might relate to a physiologic normal sinus tachycardia versus a pathological tachycardia. That is, assuming *arguendo* that Alt contained some suggestion motivating one of skill in the art to combine heart rate, activity *and blood pressure metrics* into an ICD Alt is essentially inoperable.

Third, in the Office Action at page 4 (first paragraph) the Examiner fails to supply any reference for the assertion that "The heart rate threshold increases and decreases

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based on non-ECG sensor output (hemodynamic parameter / physiologically-sensed condition / hemodynamic measurement)." Applicant objects to this assertion. However, given the narrow disclosure contained in Alt Applicant reads the assertion as actually implying that Examiner likely and fairly intended to insert (again) the word "activity" (i.e., "non-ECG *activity* sensor output"). Applicant points out that the Examiner has only cited albeit *colored passages* from the background of Alt. No citation contained in the rejection appears to relate to any portion of the invention Alt considered the invention! Applicant suggests that if the background of Alt is used in support of the instant rejection that perhaps the Examiner should supply a more focused primary reference in attempting to render a *prima facie* obviousness rejection.

Since according to the foregoing the Examiner has failed to meet the burden of establishing that Alt is a credible reference and thus that the asserted combination of Alt and Bardy is inherently flawed (i.e., does not constitute a *prima facie* obviousness rejection), Applicant respectfully requests that said rejection be withdrawn.

With respect to Bardy, a defibrillator having an arrhythmia detection capability to distinguish high rate monomorphic ventricular tachycardia from ventricular fibrillation. Bardy teaches to activate the tachycardia/fibrillation discrimination function upon detection of a high heart rate. The discrimination function operates to determine the beat-to-beat variability of the measured heart rate intervals. Fibrillation is determined to exist if the beat-to-beat variability over a physician-programmable predetermined number of intervals exceeds a predetermined variability threshold.

In summary, Alt teaches to use patient physical activity level to determine whether a high heart rate is pathologic or physiologic (i.e., whether it is due to

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pathologic tachycardia or a response to physical exertion). Bardy teaches to discriminate between high rate tachycardia and fibrillation on the basis of beat-to-beat variability after a high heart rate has been detected.

The Examiner attempts to combine the references (without any providing any showing of the desirability, motivation or suggestion for such a combination from either Alt or Bardy) and concludes that the claimed subject matter of the present invention is obvious. Applicant contends that both Alt and Bardy are devoid of any teaching or disclosure regarding use of only direct hemodynamic measurements and heart rate measurements to distinguish between tachycardia episodes. Furthermore, both Alt and Bardy are devoid of any appropriate blood pressure sensors, signal handling, and any direct relationships between heart rate, blood pressure and tachycardia status.

Accordingly, modifying the PCD of Alt to include an NID threshold as disclosed in Bardy does not result in the claimed subject matter of claims 1 and 20. As set forth in claims 1 and 20, a different NID for tachycardia detection is invoked depending upon whether a blood pressure sensor detects a substantial drop in blood pressure when there is detection of a heart rate greater than the heart rate threshold value. If a substantial drop in blood pressure is detected, a lower NID is invoked for tachycardia detection.

Applicant submits that all pending claims are in condition for allowance and requests that a notice of allowance should be issued in due course.

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Claim Objection

Claim 20 was objected to because of an apparent grammatical issue and Applicant thanks the Examiner for suggesting corrections to solve said issue. Accordingly, herein claim 20 is amended herewith along the lines suggested by the Examiner.

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Respectfully submitted,

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